Metabolic and hepatic effects of bloodletting in dysmetabolic iron overload syndrome: A randomized controlled study in 274 patients

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Résumé en anglais	Dysmetabolic iron overload syndrome (DIOS) is a common cause of hyperferritinemia, accounting for a mild increase of iron stores in insulin-resistant subjects. Iron removal could improve insulin sensitivity. We performed a prospective, randomized, controlled trial (NCT01015525) in nondiabetic DIOS patients with hepatic iron >50 µmol/g at magnetic resonance imaging to compare the metabolic and hepatic outcomes of 1-year maintenance of serum ferritin levels <50 µg/L by bloodletting associated with lifestyle and diet advice (LFDA) to those of LFDA only. Patients were randomly assigned (1:1) with stratification by center (n = 8) and hyperglycemia (>5.6 mmol/L). Sample size was calculated to provide 90% power and a difference in fasting glycemia of 0.25 mmol/L. Analysis was done in an intention-to-treat population. In 2010-2014, 146 patients were randomly assigned to receive venesections with LFDA and 128 to LFDA only. At the end of the study, comparison of iron-depleted patients and controls showed ferritin levels 71 ± 48 µg/L after removal of 4.9 ± 1.6 L of blood versus 733 ± 277 µg/L (P < 0.0001), glycemia 5.44 ± 0.7 versus 5.49 ± 0.7 mmol/L (P = 0.57), body weight +0.5 ± 4.3% versus -0.6 ± 3.3% (P = 0.03), homeostasis model of assessment of insulin resistance 3.39 versus 2.40 (P = 0.002), alanine aminotransaminase 33 ± 22 versus 37 ± 21 IU/L (P = 0.10), aspartate aminotransaminase 27 ± 13 versus 27 ± 10 IU/L (P = 0.81), gamma-glutamyl transferase 54 ± 138 versus 49 ± 35 IU/L (P = 0.72), Fatty Liver Index 58.9 ± 24.6 versus 61.2 ± 22.9 (P = 0.37), and Fibrosis-4 score 1.5 ± 0.6 versus 1.30 ± 0.6 (P = 0.51). Fatigue occurred in 25.3% of venesected patients versus 2.3% of controls (P < 0.0001). In the subgroup of patients who lost weight, glycemia, homeostasis model of assessment of insulin resistance, serum ferritin, lipid profile, and liver function tests improved irrespective of bloodletting. CONCLUSION: In DIOS patients, iron depletion by bloodletting does not improve metabolic and hepatic features, is associated with weight gain, and is not as well tolerated as expected; sustained modification of diet and lifestyle habits remains the first therapeutic intervention in DIOS. (Hepatology 2017;65:465-474).
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